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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,612	07/26/2006	Patricia Denny	19644-005US1	6177
26181	7590	07/13/2007		
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER COOK, LISA V	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 07/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,612	<b>Applicant(s)</b> DENNY ET AL.	
	<b>Examiner</b> Lisa V. Cook	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15, 16, 26, 29, 48, 49 and 54-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15, 16, 26, 29, 48, 49 and 54-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/14/06 &amp; 2/21/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Preliminary Amendment Entry***

1. The preliminary amendment filed 9/30/05 is acknowledged. In the amendment filed therein claims 10-14, 17-25, 27, 28, 30-47, and 50-53 were cancelled without prejudice or disclaimer. Currently claims 1-9, 15-16, 26, 29, 48-49 and 54-60 are pending and under consideration.

### ***Information Disclosure Statement***

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

3. The information disclosure statement filed 2/21/07 has been considered as to the merits before First Action.

4. The information disclosure statement filed 7/14/06 has been considered as to the merits before First Action.

### ***Drawings***

5. The informal drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures.

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For example, see the hand written labels and notes on the drawings, especially figure 20. Also the figure have multiple labels. See Figure 20 is labeled as figure 15 and 20. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

### *Specification*

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The disclosure is objected to because of the following informalities:

A. The first page of the disclosure is not numbered. Appropriate correction is required.

7. The use of the trademarks has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. For example, see SEPHAROSE on page 36 line 23.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Abstract*

8. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

9. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

10. The abstract in application number WO 2004/089187 includes legal phraseology "said" and "comprises". Appropriate correction is required.

### ***Claim Objections***

11. Claims 4, 5, 6, 7, 8, 9, 29, and 54 are objected to because of the following informalities: Claims 4, 5, 6, 7, 8, 9, 29, and 54 utilize acronyms (see DSL, ECL, PSA, PNA, MALI, AAL, DMF, etc). Although the terms may have art-recognized meanings, it is not clear if applicant intends to claim any prior art definition of the abbreviations. The terms should be defined in their first instance. The initial explanation will convey intended meaning of subsequent abbreviations in the claims. Please define in the claims in order to obviate this objection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 29, 55 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "early onset dental caries" in claim 29 is a relative term, which renders the claim indefinite. The term "early onset dental caries" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear if Applicant intends to mean early stages of the disorder and how such early stages can be determine. Appropriate correct is required.

B. Claim 55 is vague and indefinite because it is not clear as to what a Western blot format is to encompass. The claim is directed to a kit (product) and therefore is not further limited by process/procedures. It is suggested that the claim clearly recite the intended products that would be utilized in a Western format in order to obviate this rejection.

C. In claim 59, the use of "parenthesis" is vague and indefinite because it is not clear if the enclosed limitations are apart of the claim. If applicant intends to give weight to the enclosed information, it should written into the claim language without the use of a parenthesis. Please clarify.

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***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1-4, 9, 16, 26, 29 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161).

Seemann et al. disclose a method of evaluating high and low caries susceptibility in children. See abstract. Unstimulated saliva was allowed to accumulate in the oral cavity and the children were asked to spit out the saliva into a polypropylene sputum cup. Stimulated samples were also collected and measured. See page 157 –Collection of Saliva. In the assay a salivary sample is simultaneously incubated with a purified biotinylated lectin on a microtitre plated precoated with a neoglycoprotein. Lectin binding to immobilized glycoproteins was quantified by the streptavidin-peroxidase detection system. See page 158 - 1<sup>st</sup> column and figure 1. The patient samples were measured in the microtitre assay (device with 1<sup>st</sup> matrix material) against control saliva samples of a known concentration (see baseline, 2year caries, salivary flow in Table 1 on page 159). The saliva of caries free subjects (CR) showed a higher binding inhibition against the PNA lectin than the saliva of children with DMFT greater than 4 (CS). See page 158 2<sup>nd</sup> column and Table 1.

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II. Claims 56-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Rylatt et al. (WO 97/09620).

Rylatt et al. disclose test strip devices for analysis with saliva. The strips are taught to be useful in measuring the interaction of lectins and carbohydrates wherein either reagent may be immobilized for detection of the corresponding binding member. See abstract, page 6, and figures. The device and matrix compositions that are instantly claimed are also taught. See page 7 and page 10.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



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**III.** Claims 49 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Foster et al. (U.S. Patent #4,444,879).

Please see Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) as set forth above.

Although Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) teach the reagents required by the claims; they do not specifically teach the reagents in kit configurations. In other words, the references fail to teach the reagents as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example.

In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the assay reagents as taught by Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

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IV. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Shibuya et al. (US Patent #4,582,795).

Please see Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) as set forth above.

Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) differ from the instant invention in not specifically teaching the measurement of a drop of saliva in a matrix material.

However, Shibuya et al. teach a method and device for the rapid diagnosis of dental caries. The device utilizes a very small amount of saliva (drop). See abstract and column 4 lines 38-40. This device makes saliva analysis simple, quick, and at a low cost. See column 5 lines 11-17.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ a device requiring only a drop of saliva as exemplified by Shibuya et al. with the dental caries detection method of Seemann et al. because Shibuya et al. taught that their device utilizes a very small amount of saliva (drop). See abstract and column 4 lines 38-40. Further making saliva analysis simple, quick, and inexpensive. See column 5 lines 11-17.

V. Claims 5, 6, 7, 8 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Shibuya et al. (US Patent #4,582,795) in view of Sharon (1996, Adv Exp Med Biol, Vol408, pages 1-8).

Please see Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) as set forth above.

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Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) differ from the instant invention in not specifically all of the different known lectins as recited in the claims.

However, Sharon teaches that the carbohydrate lectin binding interaction is known and linked to various diseases. The various lectins can effect different species and used in disease treatment. See for example, page 1, Table 3, and Table 7.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ any of the known lectins in place of PNA, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

15. For reasons aforementioned, no claims are allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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